

**Appendix 8. Application for ethical approval****NATIONAL APPLICATION FORM FOR ETHICAL  
APPROVAL OF A RESEARCH PROJECT****NAF-2009-v1**

The application guidelines (NAFG-2009-v1) are to be read before completing this form to ensure that the questions are answered appropriately.

The electronic version of this form is formatted the same way as the paper version so that, for example, where an answer needs six lines, six lines are formatted, but where an answer only needs one line, one line is formatted. Please note the number of lines allowed for a question before answering it and make sure that you do not use extra lines.

You may find it helpful to print out the application form before completing it to help you to keep to the page limits allowed. **No extra pages should be added**, except where specified, as appendices.

The relevant paragraphs of the Operational Standard for Ethics Committees (Ministry of Health document) have been included in subject headings for reference.

The page breaks are not to be deleted as this will affect the formatting of the form.

When collating your application, please ensure that the information sheet, consent form and any attachments are placed behind the application form before copying. Applications not correctly collated, ie not in complete sets ready to be sent to committee members will be returned.

**Do not include this page with your application.**

## Checklist for Applicants – attach to front of application

Before sending your application form, please check to make sure that all relevant information has been attached. If not applicable to the application write N/A. Protocols, information sheets, consent forms, questionnaires, advertisements, letters of invitation, data collection or other study forms must have a version number and date (marked \*).

Please note: Incomplete applications will not be considered. Pending is an option only for written confirmation of Maori consultation, SCOTT approval, and Locality assessment by organisation. For multi-region studies, the documentation for one site must be complete.

Reference	Item	Yes, pending or N/A
Observational Studies Guidelines 5.11	* Study protocol – must be supplied with all applications	✓
Page 21 of NAFG, QE on NAF	* Consent form	✓
Page 23 of NAFG, QE on NAF	*Information sheet	✓
QA5.4 on NAF	* Questionnaire/interview guidelines	✓
Page 8 of NAFG, QA2 of NAF	Scientific assessment	✓
QA5.3 of NAF	Statistical report	N/A
QD2, NAFG page 8 Q A4	* Advertisement, letter of invitation	N/A
Section F of NAFG, Page 15	Evidence of Māori consultation	N/A
Part 4 of NAF	Declaration signed by principal investigator, Head of Department or Dean (for each site)	✓
Part 4, Form A or B of NAF	Accident compensation declaration correctly witnessed	N/A
NAFG page 20, NAF page 28	Form/s for registered and unregistered medicines	N/A
Pages 11 and 35 (Appendix 1) of NAFG, QB17 on NAF	Standing Committee on Therapeutic Trials (SCOTT) approval attached if drug is unregistered in New Zealand	N/A
Locality assessments form(s) NAFG pages 18-20	Completed by ethics committee if required, or completed by locality organisation(s) if received at time of submission	Pending
NAFG pages 30-32	Part 5: If there any use of tissue (includes blood, saliva, skin)	N/A
Appendix 2 of NAFG	Part 6: If the research involves any gene or genetic studies	N/A
Appendix 2 of NAFG	Part 7 if the study involves xenotransplantation	N/A
NAFG pages 33-34	Part 8 if any participants are unable to consent themselves including children	N/A
Parts 6 and 7, Appendix 2 of NAFG	GTAC approval if required	N/A
QB17 of NAF, Appendix 4 of NAFG	National Radiation Laboratory risk assessment if required	N/A
<b>Company sponsored studies</b>	Investigator brochure (if product is unregistered in New Zealand)	N/A
	Signed indemnity agreement (sponsor/institution/investigator)	N/A
	Current company insurance certificate	N/A
If yes to C.6	Evidence of sponsor indemnity insurance to cover C.6	N/A
If yes to C.6	Evidence of hospital/institution indemnity insurance to cover C.6	N/A
If yes to C.6	Evidence of Investigator indemnity insurance to cover C.6	N/A

# NATIONAL APPLICATION FORM FOR ETHICAL APPROVAL OF A RESEARCH PROJECT

Ethics reference number and  
date received  
(for office use only)

## Part 1: Basic Information

1. Full project title (include protocol number if applicable)

Towards relevant psycho-oncological intervention for men: Identifying sources of distress and developing an intervention concept

2. Short project title (lay title)

Research into the experiences of men with cancer

3. Principal investigator's name and position

Dr Christine Stephens, Associate Professor, School of Psychology,  
Massey University, Palmerston North

4. Contact address of principal investigator

School of Psychology,  
Massey University,  
Private Bag 11 222,  
Palmerston North

Work phone no.

(06) 350 5799 x 2081

Emergency no.\*

(06) 350 5799 x 2081

Fax

(06) 350 5673

Email

C.V.Stephens@massey.ac.nz

5. Principal investigator's qualifications and experience in the past five years (relevant to proposed research)

**Christine Stephens**, PhD is an associate professor and health researcher in the School of Psychology, Massey University, Palmerston North. She has many journal publications and recently published a book, *Health promotion: A psychosocial approach* (2008, Maidenhead: Open University Press). Chris is on the editorial board of *Stress and Health* and has advised government on policy relating to ageing.

Research projects for which she has recently received funding are:

- 2009-2012. Foundation for Research in Science and Technology: \$1,000,000. "The ELSI Elder" with Dr Mary Breheny, Dr Fiona Alpass, Mr Brendan Stevenson (Massey University), and Dr Kristie Carter (Otago University).
- 2008. Cancer Society of New Zealand: \$36,482. "Understanding the Issues Faced by Cancer Survivors" with Dr Don Baken.
- 2007-2012. Foundation for Research in Science and Technology: \$3,750,000. "The New Zealand Longitudinal Study of Ageing" with Dr Fiona Alpass, Mr Eljon Fitzgerald, Mr Brendan Stevenson (Massey University), Mr Charles Waldegrave, Dr Peter King (Family Centre), and Associate Professor Judith Davey (Victoria University).
- 2007-2008. Families Commission Blue Skies Fund: \$11, 442.00. "Older Adults' Experience of Family Life and Support" with Dr Mary Breheny.

6. Co-investigator's name(s), qualifications and position(s) and, if more than one locality; principal investigator at **each** locality

A	Heather Heron-Speirs, LIB(Hons), GradDipArts(Psych), MA(Hons). Papers were in clinical psychology and research. Thesis was in psycho-oncology. The present research is in psycho-oncology and towards a PhD. <i>Heather will be conducting the research under the supervision of Chris primarily, with consulting supervision from Don and John for their respective expertise (men's health, psycho-oncology, cancer more broadly, and Maori)</i>
B	Don Baken, PhD, PGDipClinPsych, Registered Clinical Psychologist and Research Co-ordinator with the Psycho-Oncology Service run jointly by Massey University PN and MidCentral DHB
C	John Waldon, PhD, MPH, HRC Eru Pomare Post Doctoral Research Fellow in Maori Health, Centre for Maori Health Research and Development, Massey University PN; member of the Cancer Control Council of New Zealand; life member of the Cancer Society of New Zealand
D	
E	<b>Note:</b> Although there are a number of 'localities' assisting with this research, their assistance is limited only to recruitment (identifying eligible patients and handing out our participant information sheet), therefore there is no 'principal investigator' at localities.
F	
G	

7.1 Address of A above

756 Foxton Road, RD 12, Levin 5572	Work phone no.	(06) 368 0471
	Emergency no.*	(06) 368 0471
	Fax	(06) 368 0471
	Email	haheron@clear.net.nz

7.2 Address of B above

Psycho-Oncology Service  
School of Psychology  
Massey University  
Turitea Campus  
Private Bag 11 222  
Palmerston North

Work phone no.	(06) 356 9099 Extn 2137
Emergency no.*	Mobile 0272 299 943
Fax	(06) 350 2264
Email	D.M.Baken@massey.ac.nz

## 7.3 Address of C above

Centre for Maori Health Research and Development  
Massey University PN 601  
Palmerston North  
Manawatu 4412

Work phone no.	(06) 350 5799, ext 2538
Emergency no.*	Mobile 027 228 2327
Fax	(06) 350 5606
Email	J.A.Waldon@massey.ac.nz

## 7.4 Address of D above


Work phone no.	
Emergency no.*	
Fax	
Email	

## 7.5 Address of E above


Work phone no.	
Emergency no.*	
Fax	
Email	

## 7.6 Address of F above


Work phone no.	
Emergency no.*	
Fax	
Email	

## 7.7 Address of G above


Work phone no.	
Emergency no.*	
Fax	
Email	

(\* option for ethics committee's information only)

## 8. Where this is supervised work

## 8.1 Supervisor's name

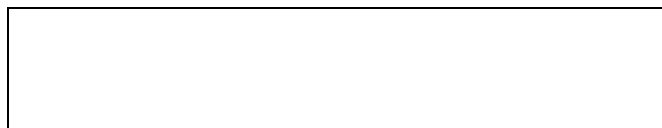
Position

Daytime phone number

Dr Chris Stephens
Associate Professor, Massey University School of Psychology, Palmerston North
(06) 350 5799 x 2081

8.2 Signature of supervisor (where relevant)

Declaration: I take responsibility for all ethical aspects of the project

A large, empty rectangular box with a thin black border, intended for a signature.

9. List locality organisation/s involved, including contact address, and complete the locality assessment in Part 4: Declarations (refer to the Guidelines (NAFG-2009-v1))

MidCentral District Health Board (including Palmerston North Regional Cancer Treatment Service)  
Gate 2B Heretaunga Street  
PO Box 2056,  
Palmerston North 4440

Taranaki District Health Board  
Private Bag 2016  
New Plymouth 4342

Whanganui District Health Board  
Private Bag 3003,  
Whanganui 4540  
Physical Address

Cancer Society of NZ, Central Districts Division (covering Horowhenua, Otaki, Whanganui and South Taranaki):  
Bronwen Laurenson, Divisional Manager  
PO Box 57  
Otaki 5542

Arohanui Hospice  
1 Heretaunga St  
Palmerston North 4414

Central PHO  
PO Box 2075  
575 Main Street  
Palmerston North

Ngati Rangi Community Health Centre Inc  
36 Burns St  
Ohakune

O Taihape Health Ltd  
3 Hospital Road  
Taihape

Ngati Ruanui Health Centre,  
78-80 Argyle Street  
Hawera

Patea Medical Trust  
1 Lincoln Street  
Patea 4520

Toiora Healthy Lifestyles Ltd  
188A Powderham Street  
P.O. Box 992  
New Plymouth

Southcare Medical Practice  
41 Hunter Street  
Hawera

Organisations that may be in a position to join the study at a later date (we will contact the HDEC if they do):

Hospice Wanganui

Hospice Taranaki

10. I wish the protocol to be heard in a closed meeting.

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Yes

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No

If the answer is yes, please provide a reason why you wish the protocol to be heard in a closed meeting in accordance with the Official Information Act 1982.

N/A

11. If the study is based, in part or in full, overseas, which countries are involved?

N/A

12. Has this application been reviewed by another ethics committee in New Zealand or overseas?

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Yes

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No

(If yes, advise which country, the name of the committee/s and the decision/s of the committee/s)

Please note a copy of the report/s may be requested.

N/A

13. **Human tissue** – Does the project involve collection or use of human tissue? If **yes**, complete Part 5.

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Yes

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No

14. **Gene studies** – Does this research involve any gene or genetic studies? If **yes**, complete Part 6.

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Yes

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No

15. **Xenotransplantation** – Does this research involve the transplantation of living biological material from one species to another? If **yes**, complete Part 7.

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Yes

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No

16. **Consent** – Are all participants able to provide consent for themselves? If **no**, complete Part 8.

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Yes

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No



17. **Lay summary** – give a brief **lay (non-technical)** summary of the study (not more than 200 words) such as you would give as an explanation to participants.

Men suffer worse cancer statistics and probably more cancer-related distress as well. They tend to be diagnosed at a later stage and make less use of services for managing distress. This may be because current services do not sufficiently match men's needs. This research aims to investigate men's particular experience of cancer in order to gain understanding which can be used to design services more attractive to them.

We want to recruit 20-40 men from Horowhenua/Otaki and Whanganui/South Taranaki so that the research will be relevant to men from districts with lower income and where people tend to have lower incomes and live further from city services. We will interview them individually about their experience of (1) cancer treatment (how they came to be diagnosed and how they made treatment decisions) and (2) cancer-related stress (including whether they used any services). The interviews should take 1-2 hours, and will be recorded and transcribed for analysis of common themes. Heather Heron-Speirs will conduct the interviews and the analysis of topic (2), while another researcher or two (yet to be selected) will analyse the rest of the data.

Some of the men interviewed will be invited to participate further, in small group discussions. These discussions will refine analysis of the data analysed by Heather, and attempt to develop an intervention concept that would meet men's needs for support with cancer distress and can be used by the Cancer Society.

18. Proposed starting date (dd/mm/yy)

01/12/10

19. Proposed finishing date (dd/mm/yy)

01/12/14

20. Duration of project in New Zealand (mm/yy)

4 years

21. Proposed final report date (mm/yy)

1/12/14

22. Has the clinical trial been registered?

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Yes

☐

N/  
A

No

If **yes**, name the register.

If **no**, has registration been applied for?

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Yes

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No

**Comment:** This is not a 'clinical trial'. Refer description of study design, Q. A3.1.

## Part 2: Ethical Principles

### A. Validity of research

(Operational standard paragraphs 53–59)

#### SCIENTIFIC BASIS

#### A1. Aims of the project

A1.1 What is the hypothesis/research question(s) and/or the specific aims of the project? (State briefly.)

- a) To identify reasons that men present early/late for cancer diagnosis and for the treatment choices they make. .
- b) To identify specific sources of the cancer-related psycho-social distress of male cancer patients, and the causes of male reluctance to use available psychosocial services.
- c) To develop an idea for (an) psychosocial intervention(s) or intervention approach that is relevant and attractive to men which can be implemented by the Cancer Society of NZ and tested (in future research) for effectiveness in mitigating distress. The concept will include a means of effectively communicating its availability to male cancer patients.

#### A2. Scientific background of the research

A2.1 Has this project been scientifically assessed by independent review?

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Yes

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No

If **yes**, describe the process, for example, HRC funding assessment process. *A copy of the report should also be attached. The researcher's response may also be included.*

The Men's Health Committee of the Cancer Society of New Zealand (National Office) reviewed and granted our application for 'Movember' funding. Our application is attachment A2.1.1 and the grant award letter is attachment A2.1.2.

If **no**, do you intend to have the project scientifically assessed and by whom?

A2.2 Describe the scientific basis of the project (**300 words maximum**). Where this space is inadequate, continue on a separate sheet of paper. *Do not* delete page breaks or renumber pages.

Although cancer is NZ's leading cause of mortality (NZ Health Information Service, 2007) cancer patients are also living longer, which means there are more survivors who face the ongoing psycho-social and existential implications of the disease. While estimates of psychological morbidity in this population vary widely, a very large representative American household survey found a significantly increased likelihood of major depression, drug dependence, and phobias in cancer patients (Honda & Goodwin, 2004). It found that the rate of male cancer patients developing depression was 533% (*sic*) of that amongst non-patients, whereas there was only an 81% higher rate in females. These rates would presumably have been higher had institutionalised patients been included in the survey. We also know that suicide risk is heightened in cancer patients (Lovejoy & Matteis, 1997; Sellick & Crooks, 1999), that general rates of suicide in NZ are higher for men than for women (3.5:1), and greater still amongst Maori and deprived people (Ministry of Health, 2010).

Meta-analyses show that male cancer patients can gain two to three times the beneficial effect from psycho-oncological intervention (Rehse and Pukrop, 2003; Heron, 2009). Patients who are older, single, and of lower income also produce stronger effects (Heron 2009). However, these demographic groups are least likely to receive psycho-social intervention (the Cancer Society confirms low uptake of their services by men and Maori, Sarah Perry pers. comm. 23 June 2010). Contributing to this mismatch is the cultural reality that men are reluctant to seek help with health – including mental health - related matters (Courtenay, 2002, 2003; Jatrana & Crampton, 2009), facing a number of barriers specific to them (McKinley, 2005).

Along with the rest of the developed world, NZ has been slow to recognise and respond to the specific health needs of men (Jones & McCreanor, 2009; Wilkens 2009). This study seeks to make a contribution towards fulfilling the specific psycho-oncological needs of men.

### A3. Study design

A3.1 Describe the study design. Where this space is inadequate, continue on a separate sheet of paper. *Do not* delete page breaks or renumber pages.

**Action research.** The overall design of this research is based on the first steps of the 'action research' cycle. That involves drawing on the expertise of people with experience - in our case, men with cancer – to collect and analyse data and to plan action (an intervention) based on it. Future research may complete the cycle by testing the intervention, gathering data on its effectiveness, then evaluating that in order to make recommendations for improvement of the intervention.

**Preliminary statistics gathering.** There is very little quantitative data available on the use of existing psycho-social services by men in NZ, but, preliminary to the main thrust of this research, we plan to collect such statistics as exist from such sources as MidCentral DHB (e.g. regarding the Psycho-Oncology Service), the Ministry of Health, and the Cancer Society of New Zealand. This data will be described quantitatively, and, where possible, comparison will be made relating to women's use of services and also relating to different cancer type, socio-economic and ethnic groups. Note that this preliminary exercise will **not** involve accessing any primary level data relating to any identifiable individual, but simply statistics on how many people have used a specified service and how many of them were men etc.

**Substantive research.** The main thrust of the research focuses on a set of individual interviews with male cancer patients, followed by team discussion with two subsets of participants drawn from among interviewees. So that this research is relevant to addressing inequalities, interview participants will be drawn from two areas of generally lower SES, greater rurality, and worse cancer statistics, namely the Horowhenua/Otaki and Whanganui/South Taranaki.

#### 1. Interviews

**Recruitment.** Potential interviewees will be early and late stage male cancer patients who have completed the most demanding phase of their treatment and are identified by their health workers (medical and radiation oncologists and specialist nurses at the Regional Cancer Service at Palmerston North Hospital, and various workers based in the community e.g. PHO cancer nurses, Cancer Society field workers, Hospice and practice nurses). Health workers will pass on an information sheet about the research during a routine appointment. The sheet will invite men to contact the researcher, Heather Heron-Speirs, to indicate interest, using a freephone number or by reply-paid post. Heather will then explain the research again verbally, and, if the man is happy to go ahead, arrange to meet for the interview at his home or other venue of his choice.

**Consent.** At the interview, Heather will begin by explaining the procedure for recording the interview and by offering \$25 fuel card to compensate for the participant's time, as indicated in the information sheet. There will be an opportunity for questions about the study including about the participant's rights. Heather will then present the informed consent form for signature.

**Content.** The interview will then commence, first with collecting some biographical details on paper (attachment A3.1), then moving to the substance of the interview, which will be digitally recorded. The substance of the interview seeks the participant's experience of (1a) entry into the medical system, (1b) treatment decision making, (2a) cancer-related distress, and (2b) use/non-use of psycho-social services (e.g. through the Cancer Society or the Psycho-Oncology service of MidCentral DHB) for assistance with such distress (refer interview schedule, attachment A5.4).

**Completion.** At the end of the interview, the participant will be thanked, reminded of his right to withdraw consent for the interview to be used at any time before transcription, told when transcription is likely to occur, and reminded of the availability of the counselling/psychological assistance. If the participant fits criteria for the team discussion phase of the research (marginalised SES or rural/small town domicile and no prior use of psycho-social services for cancer related distress), Heather will briefly describe it to him and offer an information sheet about it, inviting the man to contact her again if he is interested.

**Analysis.** Interview data will be transcribed and then analysed in two parts:

- Data on topics (1a) and (1b) above will be analysed by one or two post-graduate student researchers who have not yet been selected, but will be supervised by Dr Christine Stephens (Principal Investigator) or her appointee. The precise method of analysis for this data will be determined in discussion with these researchers, but will be more sophisticated than simple thematic analysis.
- Data on topics (2a) and (2b) will be thematically analysed by Heather Heron-Speirs.

## 2. Team discussion

It is hoped that there will be sufficient interest in the team discussion phase of the research to form two participant teams, one in each area (Horowhenua/Otaki and Whanganui/South Taranaki). The length, frequency, and locality of team meetings will be decided in consultation with participants. Petrol vouchers will be offered to compensate participants for travel to meetings.

**Content.** Team discussions will begin with refinement of Heather's initial thematic analysis of interview data (e.g. discussion of the appropriateness of her categorisations) and lead on to formulation of ideas for an effective psycho-social intervention (or approach to intervention) that is relevant and attractive to men for reducing cancer-related distress. It will include discussion of how best to communicate the availability of the intervention to men. Except for the first part of these discussions, they may involve a representative from the Cancer Society since the object is to devise an intervention that it can use and possibly trial in further research.

## A4. Participants

A4.1 How many participants do you intend to recruit? (Include details for each locality organisation.)

We wish to access men generally, but particularly from areas which suffer poorer cancer statistics and less access to psychosocial services. We will therefore draw participants from the Horowhenua/Otaki and Whanganui/South Taranaki areas. See attachment A4.2 for details of locality organisations.

Of the 20-40 participants we wish to recruit for interviews, about half will be from each district. We will not be seeking a certain number from particular locality organisations.

For the team stage, we envisage one larger or – preferably – two smaller groups of men, totalling 8-12 participants in all. If two, then one from Horowhenua/Otaki, and one from Whanganui/South Taranaki, and the researcher will relay ideas between the groups.

- A4.2 Give a justification for the number of research participants proposed, giving the details of power calculations when appropriate.

Power calculations are not applicable to this type of research.

The number of participants is intended to provide a wide variety of views during interviews, and a sufficient pool of interviewees from which to draw groups of participants for the team discussion phase.

- A4.3 If randomisation is used, explain how this will be done.

N/A

## A5. Statistical method

- A5.1 Is the method of analysis quantitative?

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Yes

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No

Or qualitative?

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Yes

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No

If the method of analysis is **wholly qualitative**, go to question A5.4.

If the method of analysis is **wholly or partly quantitative**, complete the following:

- A5.2 Describe the statistical method that will be used to analyse the data.

- A5.3 Has specialist statistical advice been obtained about this study?

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Yes

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No

If **yes**, from whom? (A brief statistical report should be included if appropriate.)

- A5.4 If the method of analysis is **wholly or partly qualitative**, specify the method. Why is this method appropriate? If interviews are to be used, include the general areas around which they will be based and a copy of the interview guide, if one is to be used. Copies of any questionnaires that will be used must be included.

A semi-**structured interview** (attachment A5.4) will be used to guide attention to the areas of research interest but allow exploration of participants' stories and insights from their perspectives.

**Thematic analysis** of interview data related to distress will collate common perspectives, but a more sophisticated form of analysis (not yet determined) will be applied to interview data related to cancer detection and treatment (refer A3.1).

Team discussion will assist with refining the analysis of interview data related to distress, as mentioned (A3.1). Further discussion with participant teams regarding the development of an intervention approach may be thematically analysed and/or developed as a visual map. However, the exact form of team discussion and the analysis of it will be decided in collaboration so it is not possible to fully predetermine either the means of data collection or analysis during that phase.

## A6. Expected outcomes or impacts of research

- A6.1 What is the potential significance of this project for improved health outcomes?

- a) The interview data related to cancer detection and treatment will contribute to understanding why men often present late for cancer diagnosis, and to their reasoning in making treatment decisions. Understanding men's unique approaches to these issues will allow for the tailoring of health promotion strategies and treatment advice to their specific needs.
- b) The interview data related to distress will contribute to understanding men's particular concerns when they have cancer, the barriers they face in accessing psycho-oncological services, and the psycho-oncological services which are acceptable to them. Again, understanding the masculine perspective – and particularly the perspective of men from disadvantaged demographic groups – will help inform the tailoring of future services to ensure relevancy and acceptability to their needs.
- c) The team discussion phase of the research is aimed at helping develop (an) intervention(s) or intervention approach (including the means of promoting it) which can be implemented by the Cancer Society of NZ, with will be seen by men as relevant and attractive, and which will be effective in reducing their cancer-related distress. Such an intervention should have an impact on rates of clinically significant distress amongst male cancer patients, including rates of depression, alcohol abuse, and suicide. It should be particularly relevant for subpopulations of men who live in areas that suffer cancer inequalities (i.e. economic deprivation, non-Pakeha ethnicity, small town/rural).

- A6.2 What is the potential significance of this project for the advancement of knowledge?

Little is known regarding specific masculine decision making approaches concerning cancer detection and treatment. Men are notoriously averse to help seeking, and their relatively poor cancer outcomes reflect a tendency towards late diagnosis. Understanding more about masculine processing of these issues is vital to producing health strategies that are effective with men, as mentioned in A6.1

There is also little research on the specific psychological needs of men in health generally and very little regarding men with cancer. Such research as exists in psycho-oncology mostly uses an hypothesis driven approach which imposes an intervention and then measures effect. Although a good effect size may be produced, invariably researchers struggle to recruit their sample. That type of research lacks ecological validity because it fails to address the reluctance of men to seek help, and is therefore of little use in practice. The challenge is to develop *means of engaging men* in psycho-social intervention. A more qualitative and exploratory/investigative approach drawing upon the expertise of men with experience of cancer will inform an intervention approach which will be both attractive to men and (with the psychological input from the researcher) effective in reducing their cancer-related distress.

### A6.3 What steps will be taken to disseminate the research results?

In relation to the interview data concerning distress (interview topics 2a&b), and the team discussions which follow:

1. PhD thesis will be written
2. Journal article publication
3. The Cancer Society will be kept fully informed throughout, will be provided with a final report, and will receive such other support in disseminating findings amongst its Divisions as is needed
4. Such promotion of the intervention as seems appropriate to the discussion teams and the Cancer Society

In relation to the interview data concerning cancer detection and treatment (interview topics 1a&b):

Honours projects and/or Masters theses will be written. The Cancer Society will be provided with a report. Publication in an academic journal and other broader dissemination is also possible, depending largely on results.

## A7. Publication of results

Will any restriction be placed on publication of results?

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Yes

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No

If **yes**, please supply details.

## A8. Funding

A8.1 How will the project be funded?

The Cancer Society of NZ (ex Movember monies) is providing the bulk of funding for this project. There is also a small allowance available to postgraduate student researchers from Massey University, and the Principal Investigator's time is also being provided by the University.

A8.2 Does the researcher, the host department, the host institution or the

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Yes

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No

locality organisation have any conflict of interest, eg, financial interest, in the outcome of this research? If **yes**, please give details.

## A9. Incentive payments

A9.1 Have you read and understood the description of incentive payments in the Guidelines?

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Yes

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No

**Note: Details about any payment (in money or kind) or reward made to participants recruited into the project are to be provided in question E10.**

A9.2 Does the funding available to the project depend upon the number of participants recruited, eg, is the funding on a per participant basis?. If **yes**, give details of the amount per participant. Where there is a significant difference between these, this incentive to recruit should be declared in the information sheet.

☐

Yes

☒

No

A9.3 Does the funding available to the project include any form of incentive (in money or kind) for the early or complete recruitment of a specified number of participants, eg, bonus payments to the researcher, host department or host institution? If **yes**, give details.

☐

Yes

☒

No

A9.4 Will **all** funding available to the project be passed through an audited research account or cost centre? If **yes**, give details. If **no**, specify why not.

☒

Yes

☐

No

Massey University Palmerston North: Research Management Services, and Resource Manager, School of Psychology.



**B. Minimisation of harm***(Operational standard paragraphs 60–68)*

- B1. How many visits/admissions of participants will this study involve? Clarify what is in addition to standard treatment. Give also an estimate of total time involved for participants.

**Interviews** are expected to take 1-2 hours each.

It is not possible to predict the frequency or length of **team discussions**, as this will be decided in collaboration with the participants, but a guess may be 3-5 meetings of a couple of hours each. Obviously, this stage of the research is dependent upon the preparedness of participants to volunteer time, so the meeting schedule will be arranged to suit them. How much the research is able to achieve will be constrained accordingly.

**Note** that participants must have completed the most demanding phases of treatment to be eligible for this research (e.g. have completed surgery and aversive chemotherapy).

- B2. Who will carry out the research procedures?

Heather Heron-Speirs will:

- Collect and describe the preliminary quantitative statistics
- Conduct the interviews and arrange for transcription
- Analyse interview data regarding topics 2a&b (re distress and psychosocial service use)
- Facilitate team discussions

Other student researchers will analyse interview data regarding topics 1a&b (re diagnosis and treatment)

- B3. What other research studies is the lead investigator currently involved with?

Refer Part 1, Q5

- B4. Where will the research procedures take place?

**Interviews** will take place in Horowhenua/Otaki and Whanganui / South Taranaki, in participants' homes or at the venue of the participants' choice (e.g. local Cancer Society rooms or other community facilities).

It is likely that **team discussions** will take place in local Cancer Society rooms, but the venue will be determined collaboratively with participants.

- B5. How do the research procedures differ from standard treatment procedures?

The objective of this research is to develop (an) intervention(s) / intervention approach that is different from what is available at present, in that it is distinctively relevant and attractive to men (refer A6.2). Further than that, it is not possible to say in advance how it will differ as the process is deliberately open to the initiative and insight of the male participants.

The actual research procedures (interviews and team discussions) are not unusual, except that in team discussions participants' opinions regarding analysis of interview data will be sought.

- B6. What are the benefits to research participants of taking part in the project?

**Interviews.** It is the Principal Investigator's experience that interviewees value and enjoy the opportunity to share their stories with a keenly interested researcher. However, in this case some participants may suffer some transient distress during the interview due to its content, which focuses on stressful cancer-related experiences. For those participants the process of explaining their journey can be expected to be therapeutic, as it will require the ordering of experiences, thoughts and feelings, which assists in making meaning from them and processing emotions.

**Team discussions.** Those men who go on to join the team discussions are expected to value and enjoy the opportunity to undertake a team project directed at helping others. Having such outward oriented work to do can again be therapeutic for cancer patients, providing them with meaning in the face of cancer and stage of life losses. For many cancer patients, diagnosis comes at the same stage of life as retirement, and men can acutely feel the impact of this 'double whammy' in stripping their self efficacy and confidence. The opportunity to use skills and wisdom built up over a lifetime and to work in a team can be highly valued and self-esteem building in such circumstances. Also, time spent in discussion with other men who have cancer may take on personally supportive aspects, and supportive relationships may develop which may continue after the research is complete.

It is typical of men in psycho-oncology research to value the opportunity to make a contribution to science which will help other people.

- B7. Describe any methods for obtaining information. Attach questionnaires and interview guidelines. (If National Health Index (NHI) information is used, see the Guidelines (NAFG-2009-v1).)

1. The gathering together of such **quantitative statistics** (not individual records) as are already held by the Cancer Society and public agencies will be done simply by making request of those bodies and by searching for sources on the web.
2. **Individual interviews.** The interview schedule is attachment A5.4.
3. **Team discussion** will refine the categorisations produced by preliminary analysis of interview data, and develop ideas for an intervention or intervention approach, including promotion to men. The latter discussion may be conducted like a focus group, with thematic analysis of data, or may use a simple 'brain storming' approach with development of ideas through visual mapping. The procedure will be worked out in collaboration with participants.

- B8. Briefly describe the inclusion/exclusion criteria and include the relevant page number(s) of the protocol or investigator's brochure.

Refer Protocol (attachment B8) pp 2-3.

We recognise that our participants are competent adults, so our approach is to empower them to make their own judgments regarding their ability to participate given clear information about the research. Our main concerns are therefore to check that cognitive competence is not significantly compromised, and that the participant has sufficient means to communicate.

### **Interviews**

Inclusion criteria:

- Adult (18 years and over) male diagnosed with cancer
- living in Horowhenua/Otaki or Whanganui/South Taranaki area
- Stage of cancer treatment required:
  - a) If patient was treated curatively, he is through the most demanding phase of treatment (e.g. surgery and chemotherapy) but within 6 months of the completion of that phase (e.g. within 6 months of having been able to return to work if it had been necessary to take leave for treatment), OR
  - b) Patient has been diagnosed with prostate cancer and is 'watchful waiting', OR
  - c) Patient is being treated palliatively or is in ongoing care for recurrent illness (e.g. leukemia).
- Speaks English sufficiently to explain his own thoughts and feelings

Exclusion criteria:

- Obvious significant cognitive deficit (e.g. dementia, intellectual disability) or serious psychiatric disorder (e.g. active psychosis, severe depression)

### **Team discussions**

Inclusion criteria:

- Has qualified for the interview phase, has sufficient life expectancy and expected independence in self-care (or accompanying support) to participate in team meetings spread over a time period of 18-24 months
- Meets one of the following socio-demographic criteria: is not currently living with a spouse or partner; is not of Pakeha ethnicity; is unemployed/retired/beneficiary; has a gross household income of <\$50,000/year
- Is able to arrange transport to meetings (with petrol vouchers to reimburse cost)

Exclusion criteria:

- Has accessed psychosocial support for cancer related issues (e.g. used the Cancer Society's 'Cancer Connect' service or 'Living Well' programme or the Psycho-Oncology Service run by Massey/MidCentral DHB)

B9. What are the physical or psychological risks or side effects to participants or third parties? Describe what action will be taken to minimise any such risks or side effects.

**Physical risks:**

**Interviews:** Fatigue may be a problem for palliative patients.

**Minimisation of harm:** The content and length of the interview is made clear in the participant information sheet. When a palliative patient expresses interest, understanding of the effort needed will be specifically raised. Palliative patients will also be phoned within 24 hours before the interview to check whether they feel up to the interview. If they appear fatigued during the interview, termination of the interview will be offered, with arrangements made for a second interview to complete the content if the participant wishes.

**Team discussions:** No risks are anticipated, except possibly fatigue, which will be handled similarly to above i.e. ensure that the participant understands clearly what the research would demand of him. It is not expected that many palliative patients will be up to participating in this phase of the research. Biographical data collected at the beginning of the interview, which includes life expectancy, will guide whether a potential team participant is offered an information sheet on this phase.

**Psychological risks:**

**Interviews.** Part of the interview focuses on cancer-related distress, and it may be distressing for some participants to recount this, or to discuss topics that they are still living through. For some it may be distressing to talk about the course of their treatment (e.g. if they are not happy with treatment advice).

**Minimisation of harm:** The topics of the interview will be made plain in the information sheet so that a man can decline participation if he thinks the interview will be too distressing for him. During the interview if distress is evident, time out or withdrawal will be offered ("Shall I pause the recorder?", "Would you like to end the interview?"). As appropriate, the interviewer will also show empathic concern, and remind the participant of his entitlement to counselling/psycho-oncological support (refer B10, below) and of his right to withdraw the recording of the interview at any time before transcription.

**Team discussions.** Although team discussions will not be so personal as the interviews, nonetheless the general topic of discussion is cancer-related distress and this may trigger distressing memories or feelings for some participants. It may also be distressing for some participants if, during the course of team work, one of the other participants learns that his condition has significantly worsened. It is also possible that a team member may behave insensitively or offensively towards others.

**Minimisation of harm:** Again, the information sheet will make the content of discussions as clear as can be anticipated so that men who are concerned can decline participation. Should any participant become distressed during discussion, time out will be offered and empathic concern expressed as appropriate. Participants will be reminded of their right to drop out at any time, and to access counselling/psycho-oncology support. 'Team rules' will be addressed at the outset, in order to establish a safe and supportive environment for participation. Such safety will include sensitivity towards other ethnicities and an agreement for participants to keep all personally identifiable information confidential.

**Note** that because we are seeking to recruit men who have completed the most aversive stage of their treatment but are still in regular touch with their health worker – through whom they will be recruited – men involved with either phase of the research will also have a ready source of reference in their health professional should they need it.

B10. What facilities/procedures and personnel are there for dealing with emergencies?

Agreement has been secured for assistance from the Psycho-Oncology Service (POS) run by Massey University/MidCentral DHB (for Horowhenua and Otaki participants) or the counselling service of the Central Districts Division of the Cancer Society (for Whanganui and South Taranaki participants) as may be required by any of the participants. Refer attachment B10.

B11. What arrangements will be made for monitoring and detecting adverse outcomes?

The men involved in this research will all be cognitively competent and will have had full information, so should be able to monitor their own distress levels to a large extent.

Researcher Heather Heron-Speirs is not a registered clinical psychologist, but she has completed clinical papers at Masters level and has personal experience of cancer, so should be sensitive to signs of elevated distress. She will raise any concerns she has with the participant concerned as described in B9 and offer follow-up counselling/psycho-oncology assistance as described in B10.

As mentioned (B9) participants will all also be still 'in the system' and in periodic contact with their health workers.

B12. If the study is a clinical trial, are participants to be provided with a card confirming their participation, medication and the contact phone number of the principal investigator? ☐ Yes ☐ No

B12.1 Do you intend to inform the participant's GP that their patient is a participant in this study? (If yes, consent from the participant is required.) ☐ Yes ☒ No

B12.2 Do you intend to inform the GP of all clinically significant abnormal results obtained during study conduct? ☐ Yes ☐ No

B13. Is the trial being reviewed by a data and safety monitoring board (DSMB)? ☐ Yes ☐ No

If **yes**, who is the funder of the DSMB?

☐ HRC ☐ Sponsor ☐ Other

If '**Other**', please specify.

B14. What are the criteria for terminating the study?

N/A

B15. Will participants be exposed to any potential toxins, mutagens or teratogens? ☐ Yes ☒ No

If **yes**, specify and outline the justification for their use.

B16. Will any radiation or radioactive substances be used? ☐ Yes ☒ No

**Note: If any form of radiation is being used, please answer B16.1–B16.2.**

**If no, go to question B17.**

B16.1 How many x-rays or other procedures are planned for the purposes of this study, ie, that are not part of standard treatment?

B16.2 Under whose licence is the radiation being used?

B16.3 Has the National Radiation Laboratory (NRL) risk assessment been completed?

☐ Yes ☒ No

If **yes**, please enclose a copy of the risk assessment and a contact name and phone number.

If **no**, please explain why not.

N/A

- B17. Will any medicines be administered for the purposes of this study? ☐ Yes ☒ No
- B17.1 If **yes**, is Standing Committee on Therapeutic Trials (SCOTT) approval required? ☐ Yes ☐ No
- B17.2 Has SCOTT approval been given? (Please attach.) ☐ Yes ☐ No
- B18. Does the study involve the use of health care resources? ☒ Yes ☐ No

If **yes**, please specify:

Recruitment of participants requires brief assistance (handing out the information sheet) by health workers at a normal appointment. Details of the locality organisations and the staff involved are provided in attachment A4.2.

- B19. What effect will this use of resources have on waiting list times for patients, that is, for diagnostic tests or for standard treatments?

None

## C. Compensation for harm suffered by participants

*(Operational standard paragraphs 87–95)*

*(Refer also to Appendix 3 of the Guidelines (NAFG-2009-v1).)*

- C1. Will participants be treated by, or at the direction of, a registered health professional as part of the research? (Treatment includes screening, diagnosis, for definitions see the Guidelines (NAFG-2009-v1) pages 11-13.) ☐ Yes ☒ No

If **no**, go to section D. If **yes**, please answer questions C2–C5.4.

- C2. Is the research being carried out principally for the benefit of a manufacturer or distributor of the drug or item in respect of which the research is taking place? ☐ Yes ☐ No

C2.1 If the answer to C2 is **yes**, please complete **Statutory Declaration Form B** and answer questions C3–C5.4.

C2.2 If the answer to C2 is **no**, please complete **Statutory Declaration Form A** and go to section D.

Depending on all the circumstances, the minimum cover that is likely to be acceptable to the ethics committee is that provided under ACC. In any case, all exclusions to compensation must be clearly and explicitly set out in the participant information sheet, including those that may be described in C5.

- C3. Is the manufacturer/distributor's agreement to provide compensation in accordance with the RMI attached? ☐ Yes ☐ No
- C4. Has the manufacturer or distributor agreed to cover any injury/adverse ☐ Yes ☐ No

consequence resulting from participation in this research?

C4.1 If no, what qualifications have been specified for cover?

**C4.2 Limiting the type of compensation**

C4.2.1 Has the manufacturer or distributor excluded any type of compensation, for example, pain and suffering, loss of earnings, loss of earning capacity, funeral costs, dependents' allowances or any other financial loss or expenses?

☐

Yes

☐

No

C4.2.2 If yes, please state what is excluded. (Include in the compensation statement on the information sheet)

**C5. Limiting liability – exclusion clauses**

C5.1 Has the manufacturer or distributor limited or excluded liability if the injury is attributable to the negligence of someone other than the manufacturer or distributor (such as negligence by the investigator, research staff, the hospital or institution, or the participant)?

☐

Yes

☐

No

C5.2 Has the manufacturer or distributor limited or excluded liability if the injury resulted from a significant deviation from the study protocol by someone other than the manufacturer or distributor?

☐

Yes

☐

No

C5.3 Is evidence of the following indemnity insurance attached?

Sponsor

☐

Yes

☐

No

If yes to either C5.1 or C5.2;

Hospital/institution

☐

Yes

☐

No

Investigator

☐

Yes

☐

No

C5.4 Is company liability limited in any other way?

☐

Yes

☐

No

If **yes**, please specify.

## D. Privacy and confidentiality

*(Operational standard paragraphs 48–56)*

D1. How will potential participants be identified?

By health workers i.e. various professionals at various locality organisations as listed in Attachment A4.2

D2. How will participants be recruited (for example, advertisements, notices)?

The health workers identified in D1 will be requested to review their case lists for patients who meet our interview criteria and pass on our information sheet to potential participants during a normal appointment.

D3. Where will potential participants be approached (for example, outpatient clinic)? If appropriate, describe by type (for example, students).

Will be approached by health workers in the course of their normal appointments (e.g. out patient clinics or at home).

D4. Who will make the initial approach to potential participants?

Health workers, as described in D2.

NB: Do not include information on storage and use of tissue samples and related information in the following questions. That is covered separately under Part 5.

D5. How will data, including audio- and videotapes, be handled and stored to safeguard confidentiality (both during and after completion of the research project)?

Data from the **interviews** will be digitally audio-recorded and either professionally transcribed (under confidentiality agreement) or transcribed by researcher Heather Heron-Speirs. Participants will be identified by pseudonym only on the recordings and in transcriptions, with the name- pseudonym list held securely and separately by researcher Heather Heron-Speirs. The transcriptions and the original recordings will be kept on CD accessible only to the research team. Computers upon which data is analysed and otherwise processed will be password protected. Raw data will not be transmitted electronically.

Data from **team discussions** will be dealt with similarly, i.e. using pseudonym identification with only Heather holding the name-pseudonym list. Participants will be required to enter into a confidentiality agreement such that identifiable particulars from group meetings are kept within the group.

D6. What will be done with the raw data when the study is finished?

CDs of raw data will be securely stored with the Principal Investigator. Name-pseudonym lists will be destroyed.



D7. How long will the data from the study be kept, and who will be responsible for their safe keeping? (Health information relating to an identifiable individual must be retained for at least 10 years, or in the case of a child, 10 years from the age of 16.)	10 years, by the Principal Investigator or, if she is no longer employed in a similar role by Massey University, by her appointee within the Massey University School of Psychology or Heather Heron-Speirs.
D8. Name those who will have access to the raw data, participant information and/or clinical records during, or after, the study?	Interview data will be accessible to Dr Christine Stephens, researcher Heather Heron-Speirs, and the other student researchers yet to be appointed and their supervisors, also yet to be appointed
D9. Describe any arrangements to make results available to participants, including whether they will be offered their audio- or videotapes.	Participants in interviews will be offered a CD of the digital audio-recording of their interviews.

## E. Informed consent

*(Operational standard paragraphs 28–43)*

A participant's informed consent should be obtained in writing, unless the procedures are not experimental and there are good reasons for not requiring written consent. If consent is not to be obtained in writing, the justification should be given and the circumstances under which consent is obtained should be recorded. Attach a copy of the information sheet and consent form provided to participants.

E1. By whom, and how, will the project be explained to potential participants?	<p><b>Interviews.</b> The researcher, Heather Heron-Speirs, will explain the study to men who contact her after reading the information sheet (attachment E1.1). She will speak to them over the phone to ensure understanding, going through the sheet paragraph by paragraph, and then arrange an interview if the man wishes to proceed. At the interview (which will be in the participants home or at another location of his choosing), questions will be invited at the outset. Written consent will then be taken.</p> <p><b>Team discussions.</b> A brief verbal explanation will be given to men who are eligible for this phase of the research at the end of their interview, and they will be left with an information sheet (attachment E1.2) providing details. The procedure from that point will be the same as for interviews i.e. men invited to contact researcher and given further information over the phone and then in person at first discussion meeting, when written consent will be taken</p>
E2. When and where will the explanation be given?	Refer E1.

E3. Will a competent interpreter be available, if required?

☐ ? Yes ☐ No

If **no**, why not?

This research is not budgeted for professional interpreter fees and therefore cannot accommodate participation by men who are not sufficiently fluent in English. (Translation by non-professionals can compromise data quality and raises ethical concerns for both the participant and the translator, so we will not allow a family member to translate.)

E4. How much time will be allowed for the potential participant to decide about taking part in the project?

Men will take as long as they wish and indicate interest by contacting Heather Heron-Speirs if and when they are ready.

E5. In what form (written, or oral) will consent be obtained? If oral consent only, state reasons.

Written. See attachment E5.

E6. If recordings are made, will participants be offered the opportunity to edit the transcripts of the recordings?

☐ Yes ☒ No

E7. Will data or other information be stored for use in a different study for which ethics committee approval would be required?

☐ Yes ☒ No

E7.1 If **yes**, please explain how.

E8. Is there any special relationship between the participants and the researchers (for example, doctor/patient, student/teacher)?

No

E9. Will there be any financial cost to the participant, for example, travel and parking costs? If so, will such cost be reimbursed? (Refer to the Guidelines (NAFG-2009-v1).)

No costs are associated with **interviews**.

**Team meetings** could involve significant travel costs for some participants since we hope to recruit some rural men. Reimbursement in the form of petrol vouchers will be offered, at a rate not exceeding 70c/km.

E10. Will any payments be made to participants, or will they gain materially in other ways from participating in this project?

☐ Yes ☒ No

E10.1 If **yes**, please supply details.

Reimbursement of travel to **team meetings** as per E9, and compensation for **interview** time in the form of a fuel card worth \$25 offered to those who participate in interviews.

## F. Cultural and social responsibility

*(Operational standard paragraphs 73–82)*

Section F enshrines two fundamental principles. They are:

- i. Culturally safe research practice: Research involving participants from specific ethnic or socially identified groups (even when small numbers from each group are involved) must involve those participant groups in the research process as full participants. Where a particular ethnic or socially

identified group is the principal subject of the research, there must be engagement with appropriate parties, and this process must be outlined in the application.

- ii. If the research is in an area of health inequalities, then the researcher must demonstrate how the research will contribute to achieving equity of outcomes for those population groups most in need within the public good health system.

F1. Have you read the HRC booklet *Guidelines for Researchers on Health Research Involving Māori*?

☒

Yes

☐

No

## Relevance and responsiveness to Māori

- F2. **All health research conducted in Aotearoa New Zealand is of relevance to Māori.** How relevant is a decision to be made by Māori. The researcher must be able to articulate the context and the relevance of the proposed research to Māori and the possible consequences for Māori health outcomes, and generally, the greater the degree of relevance to Māori, the greater the expectation of participation of Māori and hence consultation expectations.

F2.1 Given your approach to sampling, what are the anticipated numbers of Māori participants?

Interviews: 4 – 8 out of the total of 20 – 40 participants.  
Discussion teams: 2- 4 of the total of 8-12.

F2.2 What is the incidence among Māori of the health issue/disability relevant to the study?

**Life expectancy** is lower for Maori men than for men of other ethnic groups or for any women's ethnic group, and Maori men over 65 have lower hospitalisation rates than other ethnic groups (Salmond & Crampton, 2000).

Maori are disadvantaged in relation to **survival of cancers** of the bladder, colon/rectum, cervix, uterus, head/neck/larynx, and, in particular (by 3.5 times compared with non-Maori non-Pacific men) the lungs (Jeffreys et al., 2005; Shaw, Blakely, Sarfati, Fawcett, & Hill, 2005). Lung cancer is NZ's most deadly cancer, accounting for 31% of Māori and 17% of non-Māori cancer deaths. The proportion of lung cancer incidence compared with cancers of all sites is twice as high among Maori men (20%) compared with non-Maori men (10%), and lung cancer incidence is associated with deprivation (Robson, Purdie, & Cormack, 2010). It is to be noted that **socioeconomic inequalities** are evident in survival rates for nearly all cancers and this finding persists in ethnic-specific analyses and is only partially explained by differential extent of disease at diagnosis (Jeffreys et al., 2009).

The New Zealand mental health survey (Ministry of Health, 2006) showed prevalence of **mental disorder** was 29.5% for Māori, 24.4% for Pacific people and 19.3% for Others in 2006. Maori also had significantly higher rates of suicide attempts and plans even after taking other demographics into account. Economic deprivation was also significantly related to poor mental health.

Note that **Maori make up 21% of the population** of the region covered by the Palmerston North Regional Cancer Treatment Service (Cancer Control Council of New Zealand, 2010).

- F3. Please explain how this research will contribute to improving Māori health outcomes and reducing health inequalities for Māori.

We will target men with cancer who are from lower SES and small town/rural areas. Maori are disproportionately represented in these categories, as noted in F2.2 above. The first phase of the research is aimed at (1) improving our understanding of why some men present late for diagnosis, and others early, and the factors that influence their treatment decisions. This should inform more effective health promotion work in future. And (2) improving our understanding of issues relevant to the distress these men suffer.

The second phase of the research targets a subset of men from the first phase who also have *not* used available psycho-oncological services. From what little data is available (Heron, 2009, re the POS; pers comm. Sarah Penno re the Cancer Society), Maori are disproportionately represented in that group also. While the 2006 Ministry of Health New Zealand mental health survey (Ministry of Health, 2006) found that given a need for treatment, no marked socio-demographic inequality of access to health care was apparent, it also noted that people with *lower educational attainment* and people resident in *rural centres or areas* had lower rates of visits to the mental health specialty sector. Maori are disproportionately represented in these demographics. The second phase of the research will endeavour to develop (a) psycho-oncological intervention(s) / intervention approach (including a means of promoting it) that is relevant to men characterised by these characteristics, and so should benefit Maori.

By taking a 'from the grass roots up' action research approach, rather than imposing an intervention using an hypothesis driven approach, this research seeks to draw understanding of, and solutions to, the problem of access and relevance from the paradigm of the men we are targeting. The product should therefore fit their life experience and circumstance so should be of practical value.

- F4. Describe the process by which Māori have been engaged in the conception and design of the proposed research. Please identify the group/s with which consultation has taken place and outline their stated view about the proposed research. Please attach their letter/s of support for this specific research project.

Dr John Waldon was approached for his expertise in te Ao Māori and has become one of the supervisors of this research. It was after first meeting with Dr Waldon that the decision was taken to adopt an action research approach with the object of developing a relevant intervention, rather than trialling an imposed intervention (hypothesis driven approach). The whole design of the research has therefore been radically influenced by the need to ensure that it is relevant to Māori and other disadvantaged demographic minorities.

Because this research is not 'Maori research' and because participant numbers are low, consultation with Iwi has not been undertaken (therefore there are no letters of support). However, under Dr Waldon's supervision, researcher Heather Heron-Speirs will meet with kaumatua at MidCentral Health in Palmerston North in the near future. Already, under his supervision, she has met with the kaumatua of the Massey University School of Psychology, Te Harawira Turoa Haronga, and has pilot tested the interview schedule on him for cultural and general appropriateness.

The approach that we consider appropriate for this research is to discuss it with these advisors and keep in contact with them throughout the research for the purpose of exchanging ideas and obtaining ongoing advice.

- F4.1 Describe any ongoing involvement the group(s) consulted have in the project.

As mentioned, Dr John Waldon is a supervisor of this research and will be involved with it for its entirety, and it is intended that discussion with kaumatua will be ongoing throughout the research also.

- F4.2 Describe how information will be disseminated to participants and the group(s) consulted during and at the conclusion of the research project.

Dr John Waldon will be entirely abreast of the project throughout, and it is envisaged that kaumatua will be kept informed by regular meetings.

## Responsiveness to ethnic peoples

- F5. What other ethnic groups will be participating in this research based on your sampling frame (for example, Pacific peoples or Asian peoples)?

Our sampling does not specifically target such ethnic groups. However, since it targets men who are in more deprived areas and not using psychosocial services for cancer, it may include Pacifica or Asian men.

- F5.1 Are there any aspects of the research based on participation or the relevance of the research to specific ethnic groups that might raise specific cultural issues?

☐

Yes

☒

No

If **yes**, please outline.  
If **no**, go to F6.

- F5.2 How can this research contribute to reducing inequalities for ethnic peoples in the New Zealand health system?

- F5.3 Describe what consultation has taken place with specific ethnic group(s) prior to the project's development and attach evidence of their support.

N/A

- F5.4 Describe any ongoing involvement the group(s) consulted have in the project.

N/A

- F5.5 Describe how you intend to disseminate information to participants and the group(s) consulted at the end of the project.

N/A

## Responsiveness to other peoples of interest

- F6. Are there any aspects of the research based on participation or the

☒

Yes

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No

relevance of the research to specific peoples of interest that might raise specific issues for such communities (for example, for prisoners, people with disabilities, people with diverse sexual identities)?

If **yes**, please outline.  
If **no**, go to F7.

The research targets *men*, who themselves suffer health disparities. It also targets men from *small towns*, and districts with greater *socio-economic deprivation*. Such characteristics associate with higher cancer mortality (Robson, Purdie, & Cormack, 2010) and, we suspect, with lower psycho-oncological service use, and consequently poorer quality of life for cancer suffers. The second phase of the research (team discussion) selects participants from the interviewed group who have not used psycho-oncology services. Issues inherent in these disadvantaged demographic characteristics (e.g. lack of knowledge, lack of confidence with health systems, lack of transport and financial resources) are what this research is designed to appreciate and accommodate by specifically targeting these people.

F6.1 How can this research contribute to reducing inequalities for other peoples of interest in the New Zealand health system?

By improving our understanding of why some men present late for diagnosis, and others early, and the factors that influence their treatment decisions. This should inform more effective health promotion work in future.

By gaining understanding of issues relevant to the distress of the disadvantaged groups that we target and endeavouring to develop an intervention approach that is relevant to them and suited to their needs.

F6.2 Describe what consultation has taken place with specific peoples of interest group(s) prior to the project's development and attach evidence of their support.

None.

F6.3 Describe any ongoing involvement the group(s) consulted have in the project.

N/A

F6.4 Describe how you intend to disseminate information to participants and the group(s) consulted at the end of the project.

Appropriate dissemination will be a topic of discussion with the men participating in the team phase and with the Cancer Society – refer A6.3.

F7. Will the study drug/treatment continue to be available to the participant after the study ends?

☒

Yes

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No

F7.1 If **yes**, will there be a cost, and how will this be met?

Such intervention(s) as is (are) developed should be available through the Cancer Society. The Cancer Society provides services free of charge.

The counselling/psycho-oncology services which stand behind this research will also be offered on an ongoing basis to any participant who needs them, and they are also free of charge.

F7.2 If **no**, why not?

F7.3 If there was a placebo arm, what will happen to these participants at the end of the study?

N/A

**Note: This information needs to be included in the information sheet.**

## Part 3: General

Describe and discuss any ethical issues arising from this project, other than those already dealt with in your answers above.

**Gender and age disparity.** Heather Heron-Speirs is a female researcher, aged 48 years. The participants will all be male, and are likely to be 10-25 years her senior.

It could be argued that a woman could not have sufficient understanding of men to undertake this research. Although that would be an extreme position, given the history of men researching women, it is acknowledged that something of a 'culture gap' has to be bridged in undertaking this research. This will be addressed by Heather's reading the literature regarding masculinity, and particularly masculinity and health, and by her seeking the advice of her male supervisors and 'critical friends' group (comprising her male supervisors plus the male manager of the Cancer Society's Palmerston North base) formed specifically for this purpose. For example, the critical friends group met for two hours recently to provide advice regarding the interview schedule and how to approach interviewing men. Also Heather will pilot the interview schedule on men.

The gender disparity may also be regarded as an advantage in some respects. This research requires discussion of personal distress and vulnerability and it may be that a woman interviewer/group facilitator will be perceived as less personally threatening/more emotionally safe and therefore more comfortable for men to express themselves to. This safety should be reflected in the quality of data collected as interview responses and the personal depth of input into group discussions.

The age cohort to which most of the men are likely to belong is also different from the researcher, but it is not expected that any resulting difference in 'culture' will be large enough to create significant difficulties. Note that Heather has enjoyed personal experience with seniors and has also experienced a number of personal challenges in life which should assist her credibility with and ability to relate to this generation, including her own diagnosis and treatment for cancer.

**Participant age and terminal illness.** Issues can arise around the capacity of aged and ill people to give competent consent and around imposing too much burden on people who are terminally ill. However, our criteria are designed to recognise the agency of cancer patients who do not have significant cognitive weakness. Our approach is to empower potential patients to make their own voluntary choice to participate by presenting clear information, and then supporting them during participation by making allowance for fatigue and distress and backing up that support with professional counselling/psycho-oncology services in the unlikely event that they are needed. We note that the HDEC recognises that people who are terminally ill are often keen to grasp an opportunity to turn their plight into a contribution that will benefit others and should not be prevented from doing so by terminal prognosis *per se*. We support the spirit of this approach.

**Researcher self care.** It can be sad work interviewing cancer patients about their distress. Researcher Heather Heron-Speirs will be aware of the need for self care, taking time out to process feelings after interviews as may be necessary, and obtaining such supervision as necessary from Dr Don Baken who is a clinical psychologist with the Psycho-Oncology Service and a supervisor of this research.

**Thank you for your assistance in helping us assess your project fully.**

Please now complete:

- the declarations (Part 4). If there is more than one site, include a declaration for each site.

If applicable complete:

- a Registered Drug Form
- Form A or B



- Part 5
- Part 6
- Part 7
- Part 8

Attach:

- Checklist to ensure all relevant documents are attached. Incomplete applications will not be reviewed.

## Part 4: Declarations

Full project title: Male cancer patients/survivors who need - but are not accessing – psycho-oncological services: Action research to identify sources of distress and develop intervention.

Short project title: Action research to address the distress of men with cancer

### 1. Declaration by principal investigator

The information supplied in this application is, to the best of my knowledge and belief, accurate. I have considered the ethical issues involved in this research and believe that I have adequately addressed them in this application. I understand that if the protocol for this research changes in any way, I must inform the ethics committee.

Name of Principal Investigator (please print): Dr Christine Stephens

Signature of Principal Investigator:

Date:

### 2. Declaration by Head of Department in which the Principal Investigator is located or appropriate Dean or other Senior Manager

I have read the application, and it is appropriate for this research to be conducted in this department. I give my consent for the application to be forwarded to the ethics committee.

Name (please print): Dr Christine Stephens (signing as supervisor, as per note below)

Signature:  Institution: Massey University PN, School of Psychology

Date:  Designation: Associate Professor

- Where the Head of Department is also one of the investigators, the Head of Department declaration must be signed by the appropriate Dean, or other senior manager.
- If the application is for a student project, the supervisor should sign the Head of Department declaration.
- Submit a declaration by the principal investigator for each site.

### 3. Locality organisation approval

Locality organisation approval is being sought/is attached from the following locations:

Refer attachment A4.2 for a list of the locality organisations from whom assistance is being sought. At time of writing almost all had informally indicated support but needed time for formal sign off. We will forward their locality assessment documents in due course.

## Form A: Declaration of Eligibility of a Clinical Trial for Consideration of Coverage under Accident Compensation Legislation

**Instructions:** This form is to be completed and the statutory declaration signed by the most senior registered health professional providing or directing the provision of treatment as part of the research. It should be forwarded to the appropriate ethics committee together with the documents seeking ethical approval for the proposed study. The information provided must be sufficiently detailed to enable the ethics committee to be satisfied that the proposed research is not conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the research is carried out.

The provision of this information will enable the ethics committee to be satisfied that participants in the clinical trial will be considered for coverage under accident compensation legislation for injury caused as a result of their participation in the research.

### Details of proposed research study

Title of research project:

Name of research director/investigator:

Location/s of proposed study:

Number of participants:

Organisations providing support (in money or kind) for the direct and indirect costs of the research (*please provide names of organisations and details of the type of support provided*):

Relationship of proposed research to the pharmaceutical industry or other company involved in health research (*please describe the involvement of industry in your proposed research and provide details of support to be received from them*):

### Statutory declaration

I (name) of (town/city) solemnly and sincerely declare that as the most senior registered health professional providing or directing the provision of treatment as part of the research, the proposed study is not conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is carried out. I make this solemn declaration conscientiously believing the same to be true and by virtue of the Oaths and Declarations Act 1957.

\_\_\_\_\_  
Name (*please print*)

\_\_\_\_\_  
Signature

\_\_\_\_\_  
this day of

before me

\_\_\_\_\_  
Name of witness (*please print*)

\_\_\_\_\_  
Signature of witness

a Justice of the Peace, or

☐

a Solicitor of the High Court

☐

or other person authorised to take a statutory declaration.

☐

**Warning:** Please note that it is an offence under part VI subsection 111 of the Crimes Act 1961 to make a false statutory declaration. **Note:** Applicants conducting a research study that is conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is carried out should complete Form B.

## Form B: Declaration of Provision of Compensation for Injury for Participants in a Research Study for a Pharmaceutical Company or any Other Company Involved in Health Research

**Instructions:** This form is to be completed and the statutory declaration signed by the applicant. It should be forwarded to the appropriate ethics committee together with the documents seeking ethical approval for the proposed study and appropriate assurance from the pharmaceutical company or any other company involved in health research. The information provided must be sufficiently detailed to enable the ethics committee to be satisfied that:

- the proposed research is conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the research is carried out
- participants in the proposed research project will receive an acceptable level of compensation from a pharmaceutical company or any other company involved in health research in the event of injury to participants resulting from their involvement in the proposed research project.
- researchers and institutions have indemnity cover to provide an acceptable level of compensation in the event of injury to participants resulting from any researcher or research staff deviating substantially from the trial protocol.

### Details of proposed research project

Title of research project:

Name of research director/investigator:

Location of proposed study:

Number of participants:

Organisations providing support (in money or kind) for the direct and indirect costs of the research (*please provide names of organisations and details of the type of support provided*):

Relationship of proposed research to the pharmaceutical industry or other company involved in health research (*please describe the involvement of industry in your proposed research and provide details of support to be received from them*):

Details of compensation to be provided to participants in the event of injury (*documents signed by the sponsoring pharmaceutical company or other company involved in health research must be attached*):

### Statutory declaration

I (name) of (town/city) solemnly and sincerely declare that as director of the proposed research, the proposed study is conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is carried out and that in the event of injury arising from their participation in the research, an appropriate level of compensation, in line with the *New Zealand Researched Medicines Industry Guidelines on Clinical Trials – Compensation for Injury Resulting from Participation in Industry Sponsored Clinical Trials*, will be provided by (name of pharmaceutical company or another company involved in the research project) as detailed in the attached documents, unless the injury is a result of a significant deviation from the study protocol. I confirm that I, my research staff and the host institution have indemnity insurance that covers injury as a result of significant deviation from the study protocol. I make this solemn declaration conscientiously believing the same to be true and by virtue of the Oaths and Declarations Act 1957.

\_\_\_\_\_  
Name (*please print*)

\_\_\_\_\_  
Signature

\_\_\_\_\_  
this day of

before me

Name of witness ( <i>please print</i> )  a Justice of the Peace, or a Solicitor of the High Court or other person authorised to take a statutory declaration.	Signature of witness  <div style="border: 1px solid black; height: 20px; width: 100%;"></div> <div style="border: 1px solid black; height: 20px; width: 100%;"></div> <div style="border: 1px solid black; height: 20px; width: 100%;"></div>
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**Warning:** Please note that it is an offence under part VI subsection 111 of the Crimes Act 1961 to make a false statutory declaration. **Note:** Applicants conducting a research study that is not conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is carried out should complete Form A.

## Form for Registered and Unregistered Medicines (Refer Question B19)

### Information required for trials involving administration of medicines currently registered in New Zealand

This form is to be completed for all medicines including non-registered medicines except where the medicine will be given regardless of entry into the trial (eg, anaesthetic) and that medicine is not being studied in any way

Trade name of medicines	
Generic name of medicines	
Pharmacological class	
Form of administration used in the study	
Recommended dose range	
Contraindications	
Known or possible interactions with non-trial medicines the participants may be taking	
Common side effects and serious adverse reactions	
Additional information, eg, long half-life, immunosuppression	

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**Towards relevant psycho-oncological intervention for men: Identifying sources of distress and developing an intervention concept** (Heron-Speirs, Stephens, Baken & Waldon).

**List of Attachments** ...and note\*\*

**Attachment A2.1.1** Application to the Men's Health Committee of the Cancer Society of New Zealand (National Office) for Movember Funding.

**Attachment A2.1.2** Funding Grant Award from Cancer Society of New Zealand

**Attachment A3.1** Participant Biographical Details Survey

**Attachment A4.2** Locality organisation details

**Attachment A5.4** Interview Schedule

**\*\*Note:** There are a great many detailed questions in this schedule, they are repetitive and some are in relatively technical language. These are listed as a ***reminder to the researcher, and will not be used in full or verbatim***. Where the participant has limited time/strength, just the main points noted under 'purpose' will guide questioning. In every case, non-technical language will be used, and in no case will all the detail in the schedule be used, but, rather, just that selection which suits the individual's personal capabilities and experiences.

**Attachment B10** Agreement from the Psycho-Oncology Service (Massey/MidCentral) and the Counselling service of the Cancer society to provide backup counselling

**Attachment E1.1** Participant Information Sheet for Interview Phase of Research

**Attachment E1.2** Participant Information Sheet for Team Discussion Phase of Research

**Attachment E5.1** Participant Consent Form for Interview Phase of the Research

**Attachment E5.2** Participant Consent Form for Team Discussion Phase of the Research